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MAR 1 3 2010

Traditional 510 (k) Submission

Submission Date: 3/2/2010
K092427

Revised 510(k) Summary

Spinal Guides PACS
(PACS Medical Imaging Display Workstation)

Common/Classification Name:	Picture Archiving and communications system (PACS)
Classification Product Code	LLZ
Proprietary Name:	Spinal Guides PACS
510 (K) Letter Owner	Albert Davydov, DDS, PC
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Submitter's Contact person:	Albert Davydov, DDS
Date the Summary was prepared:	August 1, 2009

A. LEGALLY MARKETED PREDICATE DEVICE

The predicate device name	**Opal-Rad™**
Applicant Name	**Viztek, Inc.** 6491 Powers Ave. Jacksonville, FL 32217
510(K) Number	**K063337**
Regulation # 21 CFR	**892.2050**

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Classification Product Code **LLZ**

B. DEVICE DESCRIPTION

The device is represented by a software computer program installed on regular computers.

The device has two types of users: a web and a local user.
The web user submits an image set for processing to the local user via internet to the device's database.
The local user is viewing the images of the image set, process the image set and sends a PDF report with calculations for the web user.

Workflow details
An X-ray image is transferred to the device database by a web user. An operator (a local user) then uses a workstation to analyze AOMSI and generate a PDF report of calculations, which is then available for viewing on the web for the web user.
The local user/operator/server is installed at only one core location and X-ray images from different users are sent to the location for analyses.

The device is primarily intended for viewing digital spinal X-ray images and to prepare analyses of alteration of motion segment integrity (AOMSI).

Automated part of the reporting process

1. Automatic limitation of points placed respective to the number of vertebras
2. Automation of 4th point positioning.
3. Automatic mathematical calculations
4. Automatic notice to calibrate an image upon placement of first point on an image in image editor window
5. Automation of notification of an improper order of points
6. Automatic user password retrieval
7. Automatic submission of PDF report via e-mail to the web user

What is needed to perform the analysis?

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1. The analyses are to be performed only by a licensed medical practitioner who is knowledgeable of specific spinal anatomy and specific protocols for image analysis
2. Medical Device Spinal Guides PACS
3. Spinal pure lateral X-ray views in flexion and extension taken with the calibrator in place
4. Computer hardware
5. Internet with enough available speed

Processing

For all square vertebras the first point (I) is placed on the superior anterior external line angle of the vertebral body.

For all square vertebras the second point (II) is placed on the superior posterior external line angle of the vertebral body.

For all square vertebras the third point (III) is placed on the inferior posterior external line angle of the vertebral body.

For all square vertebras the forth point is computer generated. The 4th point (IV) is placed to the location to make the inferior side of the figure equal and parallel to the same of the upper.

For the vertebra without vertebral body (C1) the point locations are as follows:

1. The first point is placed on the Superior Anterior External Line Angle formed by dens of C2 and the most proximal point to it on C1

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2. The second point is placed on the Superior Posterior Internal Line Angle formed by radiographic laminar-pedicle junction of C1 and the superior border of C1 at the end point of that junction

3. The third point is placed on the Inferior Posterior Internal Line Angle formed radiographically by laminar-pedicle junction of C1 and the inferior border of C1 at the very end point of that junction. The forth point is computer generated, as described above

For triangular vertebra (C2):

4. The first point is placed on the Inferior Anterior External Line Angle of the vertebral body.

5. The second point is placed on the Inferior Posterior External Line Angle of the vertebral body.

6. The third point is placed on the next Superior Posterior External Line Angle formed between transverse processus of C2 and the dens of C2 vertebrae

7. The forth point is computer generated

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Once the third point is placed, the fourth one is generated by a computer. The fourth point is placed to complete a proper quadrangle to form square, parallelogram or rhombus.

The fourth point is placed by a computer to make the lower side equal and parallel to the upper side and the opposing internal line angles equal to each other.

Measuring

Before placement of points the local user has to calibrate the image.

Once we have placed the points we can relate them to each other by calculating degrees of their planes.

After the points are placed and proper geometrical figures are created the device will measure relative metric discrepancies.

The device measures relative angulation as well as specific metric relationship of shifts in millimeters and in percentages relative specific points.

Then, the data is compared with known norms and abnormalities respective to the specific points and spinal parts.

Significance of the study

In order to treat the patient better, estimate prognosis of the patient's condition and quantify the patient's impairment due to damages to the spine the AMA published certain criteria by which a doctor has to formulate a diagnosis

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and treatment plan, as well as quantify the patient's permanent impairment rating. The last edition, the 6th Edition of AMA published in 2008 specified specific limitations in norm and abnormalities for spinal evaluations of alteration of motion segment integrity calculations.

Using computerized technology installed within the device a doctor can spend almost no time in completion of otherwise lengthy mathematical calculations and get precise diagnostic report ready to apply for the best patient's care.

Once specific measurements of relationship of one vertebra to another are obtained, they are compared to norms and abnormalities.

The patient will be treated better and treatments will get better outcomes.

The individual and third party payers will save money when treatments are not indicated.

The device does not read pathologies. It is an AOMSI (alteration of motion segment integrity) specific.

Quality control functionality

1. If the order of the points placed are not followed the above protocol (not as 1, 2, 3, but 1, 3, 2) the 4th point will be placed away from the field of the column by the computer making the operator aware of the error made.

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The error figure will be seen by the local user immediately during processing.

2. No points can be placed on an image without prior calibration

3. X-ray images have to be taken with the calibrator, a small quadrangular metal plate with known dimensions. The calibrator will be affixed on the patient's skin in the designated area with the help of special, made out of paper, holder. The holder will position the metal plate vertically. The plate will be shown on an image as a quadrangle. A local user (operator) will be adjusting the image's size according to the calibrator's image and its known dimensions.

4. The image set will be reviewed for quality before the processing can be done. If images sent are not in the appropriate quality, the image set will be rejected by the local user. The web user will see the specific image set rejected and why and will consider for a resubmission a better quality image

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5. Buttons: 1) "Undo"- returns to the previous state,

2) "Zoom In"- increases the image in size,

3) "Zoom Out"- decreases the image in size,

4) "Reset to Original"- returns the image to the original size,

5) "Trace Image" guides the operator through the processing of the image

6) "Test Points" retrieves the points from the database on the processed image from the database

The architecture of the device is represented by the following diagram:

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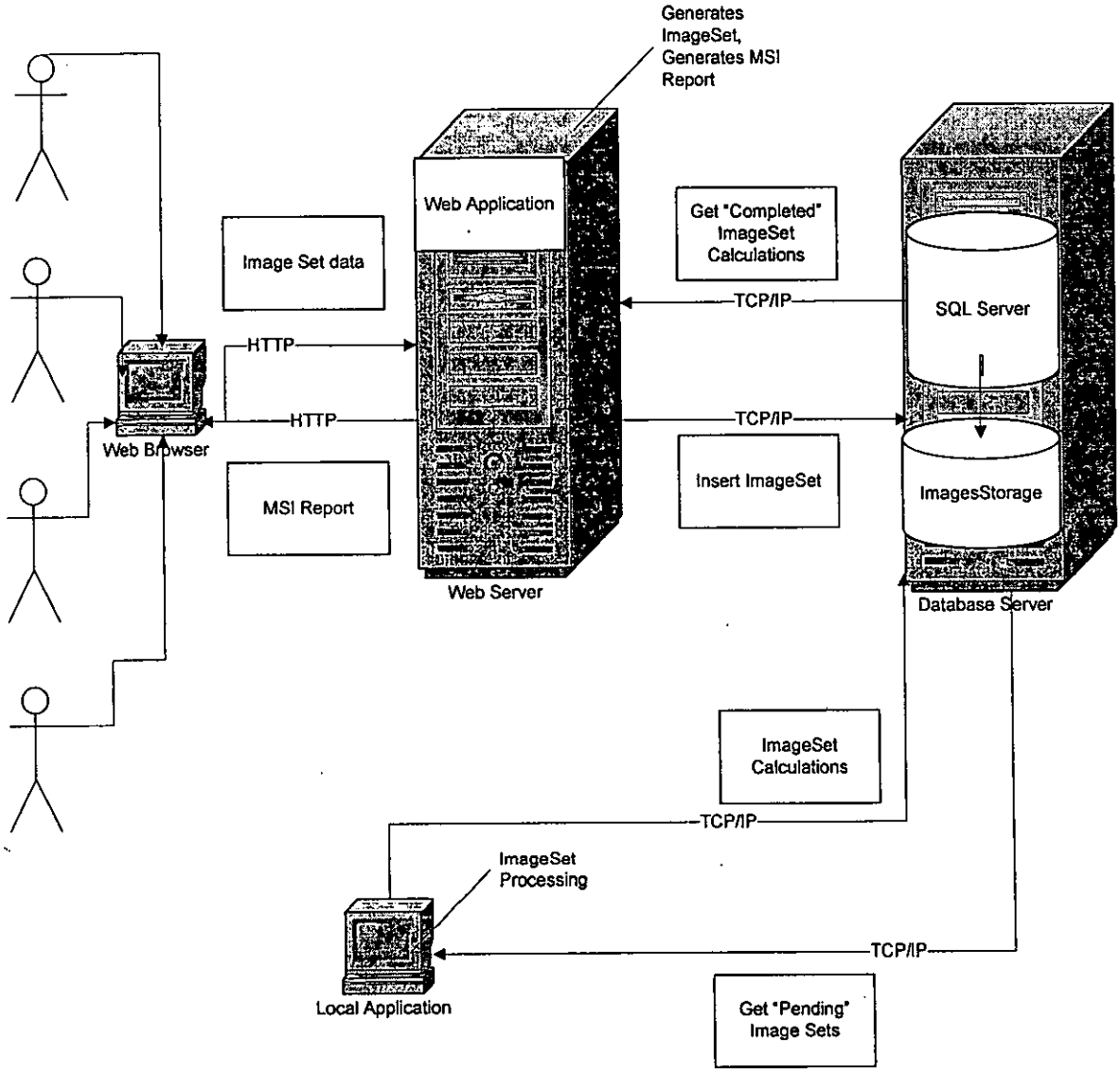

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C. INTENDED USE

Spinal Guides PACS is intended to perform: operations relating to the acceptance of spinal X-ray medical images and patient demographic information, their display, digital processing, review and editing, measurements report generation with respective storage and teleradiology exchange capabilities.

They are intended to be used by a physician to view the images and use as an aid in calculation of alteration of motion segment integrity (AOMSI) of human spine.
This device is not intended to be used for mammography images and does not require usage of 5 Mega pixel monitors.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

"Spinal Guides" PACS has substantially same indications for use as the legally marketed predicate device **Opal-Rad manufactured by Viztek, Inc., K063337** with major differences being:

1. It does not process images for mammography and does not require 5M pixel monitors, nor does it display 3D images acquired from CT and MR modalities.
2. It was created in C# computer language
3. Spinal Guides PACS were specifically made viewing of the images and for calculation of Alteration of Motion Segment Integrity (AOMS) of human spine.

This indication difference does not modify the intended use- to assist users performing quantifications and qualifications common to the general medicine, orthopedic, radiologic, and chiropractic specialty.
The new device has substantially the same control methods and operating principles as the predicate (both are computer systems and software installed in them, both intended for viewing of images) with the following major differences:

1. Images for Spinal Guides are to be taken with the calibrator affixed on the patient's skin
2. Web users are opening the images and enter all required demographic information and complete an image set for submission to database in "Pending" status
3. Local users are able to open image sets and view the images as well as process the images using automatic calculation process and formulate a PDF report turning "In process" and "Waiting for Completion" and "Complete", or turn the image sets into "Reject" to reject the image set.

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4. Once the image set turned to "Complete" by the local user the PDF report is automatically available to the web user

Descriptive characteristics and data provided in this submission are sufficiently precise, to the best of our knowledge, to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

Both the new device and the predicate are software applications installed on standard computers and servers, and utilize teleradiology via internet.

The technological characteristics are substantially the same in the proposed and predicate devices, with major differences are as follows:

1. Visual Studio 3.5.net C# programming language
2. The new device does not require usage of 5 megapixel monitors since the application is not intended to use mammography images

F. TESTING

Nonclinical tests for Spinal Guides PACS (software verification and validation) have been performed in conformance to specifications and the application is in conformance to DICOM standard PS3 NEMA 3.0 1/1/2008

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence of Spinal Guides PACS and Opal-Rad ™ as defined in the Federal Food, Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MAR 1 3 2010

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Re: K092427
Trade/Device Name: Spinal Guides PACS
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 2, 2010
Received: March 9, 2010

Dear Dr. Davydov:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

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Submission Date: 3/2/2010

Indications for use Statement

510(k) Number: K092427

Device Name: Spinal Guides PACS

Indications For Use:

Spinal Guides PACS is intended to perform: operations relating to the acceptance of spinal X-ray medical images and patient demographic information, their display, digital processing, review and editing, measurements report generation with respective storage and teleradiology exchange capabilities.
They are intended to be used by a physician to view the images and use as an aid in calculation of alteration of motion segment integrity (AOMSI) of human spine.
This device is not intended to be used for mammography images and does not require usage of 5 Mega pixel monitors.

Prescription Use ___Yes___ AND/OR Over-The-Counter Use __No___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD.
Page 1 of _____

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K092427